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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,688	12/06/2004	Yoshihiro Motomiya	MOTOMIYA1	6615

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/516,688	MOTOMIYA ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 3-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 3-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/6/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 06 December 2004 has been entered in full. Claims 1, 2 and 6 are cancelled. Claims 3-5 are under examination.

Information Disclosure Statement

The information disclosure statement(s)(IDS) filed 08 August 2005 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method for treatment of metabolic bone disease, comprising administering erythropoietin (EPO) to a patient with metabolic bone disease.

Claims 3-5 are not supported by an enabling disclosure because the specification and the art of record fail to teach the adenine-induced chronic renal failure rat model (animal model employed in the instant specification) as an animal model for *all metabolic bone diseases* such as osteoporosis, diabetic nephropathy and/or marble bone disease. Yokozawa *et al.* (Nephron 44:230-234, 1986, reference submitted by Applicant) teach that long term feeding of adenine to rats produced metabolic abnormalities resembling chronic renal failure in humans. Yokozawa *et al.* teach that long term adenine feeding provides a model which would be useful to study chronic renal failure. The instant specification teaches that bone density of the femur of the adenine animal model was measured by a bone mineral analyzer, with attention being focused on the relationship between the renal failure in this model and a decrease in bone mineral (page 2, line 23-page 3, line 1). The specification teaches that the adenine model in which renal failure developed, was a pathological animal model showing complications such as renal osteodystropy, which is a metabolic bone disease (page 3, lines 6-15). Metabolic bone disease is a broad term, which encompasses many diverse diseases/conditions. There are several other elements and etiologies, which characterize the recited diseases that are vastly different. Thus while the instant animal model may be a model for renal failure-associated osteodystropy, the specification is not enabling for treating all metabolic bone diseases.

Lastly, claims 3 and 5 are not supported by an enabling disclosure because it fails to teach the *dose effective* to treat metabolic bone disease. Thus the claims, as

recited, read on administering trace amounts of EPO instead of dosages of EPO that are effective to achieve the goal (i.e. treating metabolic bone disease).

Due to the large quantity of experimentation necessary to treat a metabolic disease comprising administering an ineffective dose of EPO and to treat all metabolic diseases based on an animal model for renal osteodystrophy, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims which fail to recite limitations regarding effective dosages of EPO to perform the recited method and which fail to recite limitations regarding which metabolic disease can be treated with EPO, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Abendroth *et al.* (Erythropoietin enhances histomorphometric signs of renal osteodystrophy. Bone (1997) Vol. 20, No. 4 SUPPL., pp. 83S. Abstract. Meeting Info: 25th European Symposium on Calcified Tissues. Harrogate, England, UK. April 25-29, 1997). Abendroth *et al.* teach a method of observing the effects of EPO treatment on

histomorphometric bone parameters in renal osteodystrophy. Abendroth *et al.* administer EPO to uremic patients on chronic dialysis. Abendroth *et al.* teach that EPO therapy in renal osteodystrophy causes an increase in bone eroded surface, osteoclasts and osteoblasts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abendroth *et al.* as applied to claim 3 above, and further in view of Nielsen *et al.* US 2002/0061849 A1. The teachings of Abendroth *et al.* are described above. Abendroth *et al.* do not teach dosages of EPO. Nielsen *et al.* teach a method of administering

EPO (0026, lines 8-10) to treat renal osteodystrophy (0032, lines 7-8). Nielsen *et al.* teach EPO dosages which overlap with the instant claim (0013, lines 5-9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of administering EPO for renal osteodystrophy as taught by Abendroth by using EPO dosages as taught by Nielsen with a reasonable expectation of success. The motivation and expected success is provided by Abendroth and Nielsen. Abendroth *et al.* demonstrate that administered EPO causes an increase in osteoclast activity in renal osteodystrophy. Nielsen *et al.* teach effective dosages of EPO used to treat various diseases such as renal osteodystrophy and various kidney disorders.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
2/2/06

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